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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,547	07/29/2003	Mark T. Marshall	P0011313.01/LG10126	7482

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EXAMINER	
BAYS, PAMELA M	

ART UNIT	PAPER NUMBER
3766	

NOTIFICATION DATE	DELIVERY MODE
10/28/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/630,547	MARSHALL ET AL.	
	Examiner	Art Unit	
	Pamela M. Bays	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-2 and 7-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 7-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 August 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. This Office Action is responsive to the amendment filed on 16 August 2010. As directed by the amendment: Claim 1 has been amended, Claims 3-6 and 17-58 have been cancelled, and no claims have been added. Thus, Claims 1-2 and 7-16 are presently pending in this application.

2. The Amendments to the Drawings have been accepted by the Examiner.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1,2, 7-10, and 16-18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Carson (US Patent Number 5,931,862, previously cited) in view of Helland (US Patent No. 5,466,254, previously cited).

5. Regarding Claims 1, 2, 17, and 18, Carson shows a medical electrical lead (Figs. 1 and 2, lead 12) comprising a first elongated body with a first elongated insulated conductor (elongated body 10', conductor 36) and a first connector at its proximal end (connector 22); a second elongated lead body with a second conductor (column 4, lines 52-63; Figs. 1 and 2, lead 10" and conductor 37) and a second connector at its proximal end (connector 24); a first low voltage electrode adapted for intimate contact with tissue to provide pacing stimulation (Figs. 2 & 3, distal pacing electrode 20, helical coil or tined

formations); a second low voltage electrode joined to the lead body in proximity to the first electrode (underlying electrode 16); and a porous layer formed over the second electrode (porous tubular covering 10); wherein the outer surface of the second electrode (16) is recessed from the outer surface of the lead body (Fig. 2) and the outer surface of the porous layer (10) is isodiametric with the outer surface of the lead body (column 2, lines 39-44). Further regarding claim 1, Carson discloses that the layer 10 covering the electrodes may be impregnated with collagen via perfusion, which is taken to reasonably disclose a sheet of collagen fibers, since the ePTFE sheet will be evenly distributed with the perfused collagen fibers (column 8, lines 50-65).

Carson discloses that the porous layer is adapted to prevent chronic tissue ingrowth (column 2, lines 47-48). The prevention of chronic tissue ingrowth, which prevents the electrode from coming in direct contact with the tissue, is a sufficient and effective means of preventing the electrode from stimulating tissue in proximity to the electrode. Alternatively, the pulse generator (Fig. 1, generator 11) of Carson must inherently contain a control means used in the art, such as a microprocessor. That control means provides a means for preventing the second electrode from stimulating the tissue as the alternate state to control-driven stimulation of tissue. If the device is off, or the second electrode channel is powered down or in a blanked state, the control means is preventing the second electrode from delivering stimulation to the tissue. However, Carson does not discloses that the first and second electrodes are located on first and second separate lead bodies, wherein the first lead/electrode is placed in a cardiac vein and the second lead/electrode is placed in the right ventricle. Helland teaches a multi-

lead cardiac pacing system (Fig. 7, Abstract) wherein each lead 150, 120, 148, 160 has a separate connector 130, 132, and wherein the first lead/electrode is placed in a cardiac vein 30 and the second lead/electrode is placed in the right ventricle 154, wherein the first and second leads act as the anode and cathode in a bipolar pacing system (Col. 5, Lines 50-67). It would have been obvious to one having ordinary skill in the art at the time of the invention to use separate leads for the separate electrodes, as taught by Helland et al, in the bipolar pacing system with electrode porous layer as disclosed by Carson, in order to allow for implantation in both the cardiac vein and the right ventricle for pacing/defibrillation therapy.

6. Regarding claims 7-10, Carson discloses a means to promote wetting comprising a wetting agent which can be a surfactant and a surface treatment of the porous layer (column 2, line 54 through column 3, line 26).

7. Regarding claim 16, Carson discloses the invention as previously recited wherein the porous layer is adapted to prevent chronic tissue ingrowth (column 2, lines 47-48).

8. Claims 11-14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Carson in view of Helland, further in view of Hull et al. (US Patent 5,269,810, previously cited).

9. Regarding Claims 11-14, Carson and Helland shows the invention substantially as claimed, but does not disclose the thickness of the porous layer (2-9 mm) or the desired size range for the pores in that layer (0.4-50 microns). In the same problem solving area, Hull'810 teaches an electrode-covering layer that is about 0.13 mm (0.005 inches) thick with fibril length (i.e. internodal distance and pore size) of 10 microns for

the advantages of being highly biocompatible, highly flexible, and long-lasting (column 3, lines 32-45; column 4, lines 1-15). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use similar structural criteria with the Carson and Helland systems for the same advantages of biocompatibility, flexibility and long lifespan (motivation to combine provided by Hull et al., column 3, lines 32-45; column 4, lines 1-15).

10. ***Claims 12-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Carson in view of Helland, further in view of Soukup et al. (US Patent 5,466,252, previously cited).***

11. Carson and Helland shows the invention substantially as claimed, but does not disclose the desired size range for the pores in that layer (0.4-50 microns). In the same field of endeavor, Soukup et al. teaches an implantable lead with a porous PTFE layer with preferred fibril lengths greater than 4 microns, and most preferably greater than 10 microns to provide the necessary amount of flexibility and extensibility for the intended application and to present an acceptable biocompatible surface to the blood chemistry to which the outer surface of the lead will be exposed (column 2, lines 26-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use similar parameters for the lead body covering in the Carson and Helland systems to provide the same advantages of flexibility and biocompatibility (motivation to combine provided by Soukup et al., column 2, lines 26-34).

12. Claim 19 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Carson in view of Helland, further in view of Kroll (US Patent 6,327,498, previously cited).

13. Carson and Helland shows the invention substantially as claimed, but does not disclose a third high voltage electrode adapted for defibrillation stimulation. In the same field of endeavor, Kroll teaches a third electrode (Fig. 2, electrode 46) placed proximal to a second electrode (32) and distal to a first electrode (34) for the purpose of providing shocking stimulation pulses (column 7, lines 64-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include a third electrode in the Carson and Helland devices for the same advantage of applying shocking stimulation (defibrillation) to the heart (motivation to combine provided by Kroll column 7, lines 64-67).

Response to Arguments

14. The Objections the Drawings have been withdrawn due to the Applicant's arguments/amendments.

15. The Rejections under 35 USC 112 have been withdrawn due to the Applicant's amendments/arguments.

16. Applicant's arguments filed 16 August 2010 with respect to the 35 USC 103 Rejections have been fully considered but they are not persuasive.

17. In response to applicant's argument that it would not have been obvious to use the lead design disclosed by Carson in separate electrodes as disclosed by Helland et al because Carson et al does not teach separate leads, the test for obviousness is not

whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

18. In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, the Helland et al reference was used to teach a two-lead system. The Carson reference discloses all of the claimed elements except for this feature, which is taught by Helland et al as described in the above rejection, and therefore the Examiner maintains that it would have been obvious to one having ordinary skill in the art at the time of the invention use separate leads for the separate electrodes, as taught by Helland et al, in the bipolar pacing system with electrode porous layer as disclosed by Carson, in order to allow for implantation in both the cardiac vein and the right ventricle for pacing/defibrillation therapy.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pamela M. Bays whose telephone number is (571)270-7852. The examiner can normally be reached on Monday-Friday, 10:30am-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/P. B./
Examiner, Art Unit 3766